

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Takashi FUJITA et al.

Art Unit: 1797

Application Number: 10/561,538

Examiner: Xiaoyun Xu

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For: SPECIFIC COMPONENT MEASURING METHOD BY SPECTRAL  
MEASUREMENT

Attorney Docket Number: 053362

Customer Number: 38834

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Takashi Fujita, a citizen of Japan, hereby declare and state the following:

1. I graduated from Japan Advanced Institute of Science and Technology University of Nobi-shi, Ishikawa, Japan in 1999 with a master degree in material science.
2. Since 1999, I have been employed by Wako Pure Chemical Industries, Ltd., of Osaka-shi, Osaka, Japan where my present title is Development of immuno reagent of automated chemiluminescence enzyme immunoassay analyzers. During my employment therein, I have conducted high sensitive reagent of chemiluminescence enzyme immunoassay, in the Diagnostics Research Laboratories.
3. I am one of the inventors for the invention of the US Patent Application No. 10/561,538.
4. I have read and am familiar with the above-identified patent application as well as the Official Action dated March 03, 2010 in the application.

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5. I have read and am familiar with the contents of cited reference(s), U. S. Patent Publication No. 2001/0038450 to McCaffrey et al.; and Engineering Materials vol.47, No.11, page 38-41 (1999) to Ryoji Miyazato, IDS with full English translation cited in the Official Actions in the above-identified application.

6. Under my supervision and control, I conducted experiments to obtain data for proving the use of Novally E which is disclosed in Ryoji Miyazato cannot accomplish the objection of the present invention.

#### 7. Experiment

##### [Preparation of reagents]

Following reagents were prepared:

A Luminescent substrate Solution: a solution of 5 mM luminol (a buffer solution exclusive for SphereLight 180, pH 8.5, Wako Pure Chemical Industries, Ltd.),

A H<sub>2</sub>O<sub>2</sub> Solution: an aqueous solution of 0.02% H<sub>2</sub>O<sub>2</sub> (an acid buffer solution exclusive for SphereLight 180, pH 3.0, Wako Pure Chemical Industries, Ltd.).

##### [Measuring Instrument]

Using SphereLight 180 which was automated chemiluminescence enzyme immunoassay analyzers (Olympus Ltd.), following instrument were used under three conditions as described below.

(1) The instrument which the anti-static tapes (20×500×0.2mm, Japan Vilene Co., Ltd.) attached transversely on four inside wall surfaces of the photometry chamber (made of

aluminum),

(2) The instrument which the Novalloy E which is persistent static elimination ABS resin ( $20 \times 500 \times 1$  mm, Daicel Polymer Ltd.) attached transversely on four inside wall surfaces of the photometry chamber (made of aluminum),

(3) The instrument in which countermeasure for preventing the influence of the electric was not provided.

As shown above, the total size of attached anti-static tape and Novalloy E were the same.

[Measurement of Luminescence]

The luminescent substrate solution of  $70 \mu\text{L}$  and  $70 \mu\text{L}$  of a  $\text{H}_2\text{O}_2$  solution prepared as above were automatically dispensed into the reactor tank of the reagent cartridge in SphereLight 180, and then, the luminescence of  $140 \mu\text{L}$  in total volume of the reaction solution was measured. Incidentally, there is a concave portion to dispense the reagent solution in the above-described reagent cartridge, and it is called as a reactor tank (or called as a measurement vessel).

Measurement was repeated 4 times (every 20 seconds in this Example) at the same interval in the same sample.

[Results]

Results are shown in Table A (Unit: cps). In Table A, "Control" means a result obtained by measuring luminescence using the measuring instrument on which an anti-static tape nor Novalloy E is not attached (Counter measure for preventing the influence of the electric charge is not provided.).

The "versus Control" (%) is shown as a ratio of the average of signal values obtained by

measuring luminescence using measuring instrument on which the anti-static tape or Novalloy E is attached, to the average of the signal value of control.

[Table A]

Number of Measurement	Control		With Anti-static Tape		with Novalloy E	
	Luminescence (cps)	versus Control	Luminescence (cps)	versus Control	Luminescence (cps)	versus Control
1	6090		2418		5261	
2	5770		2517		5177	
3	5348		2717		5325	
4	5790		2525		5158	
Average	5523	100%	2544	46%	5230	95%

As is clear from Table A, the signal values (versus Control) measured by using the measuring instrument attached the anti-static tape thereon is 46% against control. Therefore, it is understood that the measurement using anti-static tape can suppress background value.

On the other hand, the signal values (versus Control) measured by using the measuring instrument attached the Novalloy E thereon is about 95% against control. Therefore, it is understood that the measurement using Novalloy E which is persistent static elimination ABS resin cannot suppress background value.

8. McCaffrey teaches that the photo-detecting transducers used for detecting luminescence are very sensitive to static change, and a sample chamber of known devices must be made of a conductive material or some other means must be provided to remove static charge from the sample chamber. Ryoji disclose Novalloy E which is a persistent static elimination ABS resin.

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However, I have concluded, among other things, the use of Novally E cannot suppress the background value.

Therefore, the present invention has the unexpected superior effect over the combination of McCaffrey and Ryoji.

The undersigned declares that all statements made herein of his own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that willful false statements may jeopardize the validity of the application or any patent issued thereon.

Takashi Fujita  
Takashi FUJITA

Signed this 27th day of May, 2010.